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Global Medical Company

510(k) Summary

FEB 15 2013

The following 510(k) summary is submitted as required by 21 CFR Part 807.92:
Date Prepared: January 23, 2013

1. **Submission information:**

a) Submitter

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b) U.S Agent

Name	LK Consulting Group
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Phone	714-869-3080
Fax	714-409-3357
Contact	Priscilla Chung

2. **Purpose of Submission**

The purpose of this Special 510(k) is to add gamma sterilized models and additional new design models to the unmodified device (SYNSTER cages, K111820). The intended use and the principal technology of the subject device are the same as the unmodified device.

- The added sterilized models have the same design as the unmodified device.
- The additional new design models have trivial design and dimension modifications comparing to the unmodified device.

3. **Device Identification:**

Trade Name: SYNSTER® CERVICAL CAGE
SYNSTER® ALIF CAGE
SYNSTER® PLIF CAGE
SYNSTER® PTLIF CAGE
SYNSTER® TLIF CAGE
RHEA® PLIF CAGE
TALON® TLIF CAGE

Common Name: Intervertebral Body Fusion Device

Classification Name: Intervertebral Fusion Device with Bone Graft, Cervical
(21 CFR 880.3080, Product Code ODP)
Intervertebral Fusion Device with Bone Graft, Lumbar

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(21 CFR 880.3080, Product Code MAX)

4. **Identification of the Legally Marketed Devices (Predicate):**
Substantial Equivalence for the SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE, RHEA® PLIF CAGE and TALON® TLIF CAGE is based on its similarities in indications for use, design features, operational principle and material composition when compared to the predicate devices cleared under the following:

- SYNSTER CERVICAL, ALIF, PLIF, PTLIF and TLIF CAGE (K111820)
- Eminent Spine Interbody Fusion System (K090064)
- AVS PL PEEK Spacer System (K093704)
- Zyston Curve Interbody Spacer System (K110650)
- AnyPlus ALIF, PLIF, and TLIF PEEK Lumbar Cage (K100516)
- Genesys Spine Interbody Fusion System (K103034)

5. **Device Description:**
The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE, RHEA® PLIF CAGE and TALON® TLIF CAGE will be offered in various device configurations based on surgical approach and patient anatomy, and consist of:

1) Cervical Interbody Fusion Device (SYNSTER® CERVICAL CAGE), which may be implanted as a single device via an anterior approach.

2) Lumbar Interbody Fusion Device [SYNSTER® (ALIF, PLIF, PTLIF and TLIF) CAGE, RHEA® PLIF CAGE and TALON® TLIF CAGE], which may be implanted
   - As a single device via an Anterior or Anterolateral or Lateral (ALIF) approach;
   - Bi-laterally via a posterior (PLIF) approach;
   - As a single device via a posterior transforaminal (PTLIF) approach;
   - As a single device via a transforaminal (TLIF) approach.

The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF) CAGE, RHEA® PLIF CAGE and TALON® TLIF CAGE components are made of polyether ether ketone (PEEK OPTIMA® LT1) that conforms to ASTM F2026, and is supplied as non-sterile and/or gamma sterile. Additionally, the devices contain titanium makers (ASTM F136) to assist the surgeon with proper placement of the device.
The SYNSTER® (CERVICAL, ALIF, PLIF, PTLIF and TLIF, RHEA® PLIF CAGE and TALON® TLIF CAGE are implanted by using the instruments specially designed and manufactured from stainless steel materials that conform to ASTM F899.

6. **Indications for Use:**
The SYNSTER CERVICAL CAGE are indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc

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confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The SYNSTER (ALIF, PLIF, PTLIF and TLIF) CAGE, RHEA® PLIF CAGE and TALON® TLIF CAGE are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The devices are intended for use at one level or two continuous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

7. **Summary of Technology Characteristics:**
The subject system possesses the same technological characteristics as the predicates. These include similar heights, widths, lengths, and intended use.

8. **Discussion of Non-clinical Testing**
The following non-clinical tests were conducted:
   - Sterility test (ISO 11737-1)
   - Shelf Life Validation Test
   - Mechanical and Physical Studies on gamma-sterilized PEEK-OPTIMA
   - Mechanical Testing in accordance with ASTM F2077-03 and ASTM F2267-04 for TALON® TLIF CAGE
     - Static axial compression testing
     - Static torsion testing
     - Static compression-shear testing
     - Dynamic axial compression testing
     - Subsidence testing

9. **Conclusions**
The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. The non-clinical testing mentioned above has been conducted to validate that the modifications do not raise issues of safety and performance. Results from the studies demonstrate that the subject devices are substantially equivalent to the referenced predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter dated: February 15, 2013

BM KOREA Co., Ltd.
% LK Consulting Group USA, Incorporated
Ms. Priscilla Chung
Regulatory Affairs Consultant
951 Starbuck Street, Unit J
Fullerton, California 92833

Re: K122518
Trade/Device Name: SYNSTER® CERVICAL CAGE, SYNSTER® ALIF CAGE, SYNSTER® PLIF CAGE, SYNSTER® PTLIF CAGE, SYNSTER® TLIF CAGE, RHEA® PLIF CAGE and TALON® TLIF CAGE
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: January 29, 2013
Received: January 30, 2013

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K122518

Device Name: SYNSTER® CERVICAL CAGE, SYNSTER® ALIF CAGE, SYNSTER® PLIF CAGE, SYNSTER® PTLIF CAGE, SYNSTER® TLIF CAGE, RHEA® PLIF CAGE and TALON® TLIF CAGE

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Prescription Use ___X___ (Part 21CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephanie Bechtold -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122518